

# WAYNE J. COLTON, INC.

Patent Prosecution ~ United States Patent and Trademark Office

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November 2, 1999

PATENTS

Box Patent Application  
Assistant Comm'r for Patents  
Washington, D.C. 20231

RE:   Invention Title       FOOT MOUNTED VENOUS COMPRESSION DEVICE  
      Serial Number       08/428,268  
      Filing Date         April 25, 1995  
      Inventor(s)         Cesar Z. LINA  
  
      Docket Number       1001.1012

Dear Sir:

Enclosed herewith for filing in the above referenced matter, please find the following:

1. Application for Letters Patent;
2. Petition to Make Special on the Grounds of Actual Infringement;
3. Declaration, Power of Agent and Correspondence Address;
4. Power of Attorney and Intervention of Assignee;
5. Certificate under 37 CFR §3.73(b);
6. Information Disclosure Statement;
7. Form PTO-1449 (with cited references); and
8. Addressed postcard to be returned upon receipt.

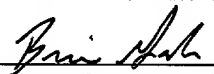
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Printed Name of Person Mailing

WAYNE J. COLTON, INC.

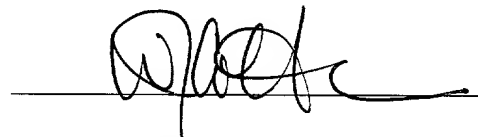
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Respectfully submitted,

Dated: 11/02/99

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Docket No. 1001.1096

APPLICATION FOR LETTERS PATENT  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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## FOOT MOUNTED VENOUS COMPRESSION DEVICE

### RELATED APPLICATIONS:

This application is a continuation of Applicant's co-pending U.S. patent application  
5 Serial No. 08/816,807 filed March 19, 1997, which is a continuation of U.S. patent application  
Serial No. 08/428,268 filed April 25, 1995, now abandoned, which is a continuation of U.S.  
patent application Serial No. 08/275,920 filed July 14, 1994, now abandoned, which is a  
continuation of U.S. patent application Serial No. 08/000,545 filed January 4, 1993, now  
abandoned, which is a continuation of U.S. patent application Serial No. 07/766,576 filed  
10 September 27, 1991, now abandoned. By this reference, the full disclosures, including the claims  
and drawings, of U.S. patent applications Serial No. 08/816,807, Serial No. 08/428,268, Serial  
No. 08/275,920, Serial No. 08/000,545, and Serial No. 07/766,576 are incorporated herein as  
though now set forth in their respective entireties.

### 15 BACKGROUND OF THE INVENTION:

Field of the Invention. The present invention relates to massage devices which apply  
pressure to the body. More particularly, the invention is in the class of medical devices which  
utilize cyclic pressure to aid blood circulation in the limbs of a human body.

Related Art. Medical devices that apply cyclic pressure to a person's legs, arms and/or  
20 feet are very old and well-known in the art. Many have employed pulsating pads or plungers for  
improving circulation. Others have used hydraulic and pneumatic bladders for the same and for  
many other purposes. The shapes, sizes, and composition of such bladders and pads are widely  
varied, depending largely on their particular application.

Man has known the fundamental principle of most cyclic compression devices for  
25 thousands of years. They are merely a more recent embodiment of the old art of massage, which

has been used to stimulate circulation since prehistory. Use of mechanical devices to effect the massaging action is obviously more recent, but has a clear history of more than 150 years.

Full understanding of the mechanism involved in this form of improving blood flow is more recent but has not fundamentally changed the devices used to accomplish this result. Veins are now known to contain a series of one-way check valves along their length. Thus, when pressure is applied, compressing a vein, the fluid expelled therefrom can only proceed in the direction of normal circulation. When such compression is relaxed, the vein returns to its normal circular cross-section, and the flow of blood into the vein is increased until it reaches its normal state of back pressure. Repeating this cycle in a cyclic fashion thus increases blood flow in the normal direction of circulation.

Such compression/decompression cycles occur naturally in humans as part of the action of the muscles and flexure of the limbs. It has been known for many years that the arch of the foot includes a large venous plexus (or group of veins). It is also known that this venous plexus is compressed during normal walking or running, thereby stimulating circulation. This efficient circulation aid is a marvelous design by our Creator, as its effect is greatest when the leg muscles (the largest muscles in the body) are in action and need the oxygen supplied by enhanced circulation.

For these and other reasons, the foot has long been known as an effective site for applying cyclic pressure. For instance, many devices such as Massator's "PediPulsor" improve circulation by positioning a pulsating, dome-shaped pad in the arch of the foot. Many others have targeted the arch of the foot with flexible pneumatic chambers. A partial sampling of such pneumatic devices that target the arch of the foot includes Japanese utility model No. 47-10392, U.S. patent No. 4,614,180 issued to Gardner *et al.* and U.S. patent No. 4,941,458 issued to Taheri.

Many others have long recognized that the foot contains veins that can be massaged or pumped to provide better circulation. Some examples are: L.E. Corcoran, who states in his U.S. patent No. 2,880,721 issued April 7, 1959 that massaging the soles of the feet "promotes a beneficial degree of circulation;" Richard Dillon, M.D., whose Journal of Vascular Diseases, January 1986 report entitled "Treatment of Resistant Venous Stasis Ulcers and Dermatitis with the End-Diastolic Pneumatic Compression Boot" on treatment of circulation-impaired patients states "compression boot therapy enjoys a 173 year history;" and P. Gaskell, M.D. and J.C.W. Parrot, M.D., whose Surgery, Gynecology, and Obstetrics, April 1978 report entitled "The Effect of Mechanical Venous Pump on the Circulation of the Feet in the Presence of Arterial Obstruction" shows a high level of understanding of the process of venous pumping with pulsed air by stating "[w]e have found that the boot covering the foot alone is simpler, less cumbersome, and gives a greater reduction of venous pressure than either a large cuff which covers the whole calf or a boot which includes the calf and the foot."

#### SUMMARY OF THE INVENTION:

The present invention is directed toward improving upon the teachings of the prior art, uniquely integrating various concepts and features to provide a significant advancement in the field. A primary object of the invention is to provide a small, lightweight and comfortable device, preferably suitable for prolonged wear, which helps prevent and/or solve many of the problems associated with impaired circulation.

Another object includes providing a pneumatic device which encloses only limited portions of the foot, especially those portions which may be readily compressed to improve circulation. Related objects include providing comfort and moisture control and avoiding the need for accessories such as additional stockings, wraps, sandals, straps, and the like, which have been required by the prior art.

Another object of the present invention is to provide an intermittent compression device requiring a minimum volume of air per pulsation.

Another object is to provide a blood circulation aid which will fit a wide variety of patients without requiring any modification or adjustments.

5 Another object is to provide a device of great simplicity and ease-of-use in contrast to other devices designed for the purpose of aiding blood flow in the feet and legs.

Another object of the invention is to provide a blood flow improvement device which, due to its inherent low manufacturing cost, is practical to use as a disposable item rather than cleaning and reusing.

10 The present invention addresses the foregoing and many other objects by providing an ingenious article that integrates a compression bladder and its entire mounting, stabilizing and adjustment systems into a simple and economical construction.

The present invention comprises a foot wrap device made from two sheets of fabric sewn or welded together to form an inflatable pocket or bladder in part of the main body area. One aspect of the invention relates to its roughly T-shaped configuration, with at least one extension from the main body area for encompassing the foot's arch. A second extension preferably extends from the main body in a direction opposite the first. A third extension from the main body is roughly perpendicular to the arch-encompassing extensions, for embracing the back of the heel. In the preferred embodiment, both inner and outer fabric layers are cut from the same pattern.

20 Fasteners formed integral with two of the extensions enable releasable application on the foot. Preferably, such fasteners include trademark "VELCRO" hook connectors, and the outer surface of the foot wrap is formed of trademark "VELCRO" loop material (or the equivalent) for mating with the hooked fasteners. The inner layer of the foot wrap is a vapor permeable material having greater elasticity than the outer layer. Both fabrics are preferably impermeable to air and

capable of being fused together by heat welding. A filling tube is sealed into said inflatable bladder through the outer fabric layer.

In the preferred embodiment, the complete foot wrap weighs only a few ounces and is soft and pliable. When the device is properly applied, the inflatable bladder lies under the arch of the foot. One extension wraps over the instep to completely surround the foot and fastens to the outside surface of the main body section. The second extension wraps around behind the heel and also fastens to the outside surface of the main body section, thus securely holding the device in place on the foot to hold the bladder in place when it is inflated. Fluid for such extension is supplied in a pulsed sequence selected for frequency and intensity by the physician from one of the pump/control systems well known in the art.

Numerous other features, advantages, and objects of the invention will evident from the following more detailed description of certain preferred embodiments, particularly when considered together with the accompanying drawings and appended claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS:

Figure 1 shows a first embodiment of the present invention in the form of a foot wrap 1, particularly showing the outer surface of the foot wrap as it is laid out flat.

Figure 2 shows a view of the inner surface of the foot wrap 1 laid flat.

Figure 3 shows a top view of the foot wrap 1 in place on a human foot.

Figure 4 shows a side view of the foot wrap 1 in place on a human foot.

Figure 5 shows a cross section of the foot wrap 1 sectioned along plane "A-A" shown in Figure 2.

Figure 6 shows the same cross section as in Figure 5, except that bladder 9 is shown inflated in Figure 6.



Figure 7 shows a second embodiment of the present invention in the form of a foot wrap 1', laid out flat in the same manner as foot wrap 1 in Figure 1.

Figure 8 shows a view of the inner surface of the foot wrap 1' laid flat.

Figure 9 shows a top view of the foot wrap 1' in place on a human foot.

5 Figure 10 shows a side view of the foot wrap 1' in place on a human foot.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:

Referring to Figures 1-6, a first embodiment of the present invention is shown in the form of foot wrap 1. In Figure 1, foot wrap 1 is shown open (i.e., laid out flat), with the outer surface of foot wrap 1 facing the viewer. Figure 2 is a view from the opposite side showing the inner surface of foot wrap 1. Figure 5 is a cross section along line "A-A" of Figure 2 and generally illustrates the construction of the foot wrap. The foot wrap 1 is generally formed of two sheets 2 and 3 which are bonded together to form a bladder 9 with tabs 4, 5 and 7 extending away from the bladder 9. Foot wrap 1 also includes a fluid inlet 11 (also referred to as "fitting 11") for inflating and deflating the bladder 9, as well as fasteners 6 and 8 for releasably securing the wrap 1 on a foot (designated as foot 100 in the drawings). To the extent any of these basic components are not otherwise readily available through numerous manufacturers, they can be obtained or located through Kinetic Concepts, Inc. in San Antonio, Texas.

Referring primarily to Figure 5, sheet 2 is preferably cut from a robust, non-stretch fabric. The outer surface of sheet 2 (i.e., the surface facing away from sheet 3) has loops like those found on trademark "VELCRO" loop material, which are compatible to releasably engage trademark "VELCRO" hook material. The interior surface of sheet 2 (i.e., the surface facing toward sheet 3) is heat-weldable. Sheet 2, thus, is referred to as a sheet of laminated loop fabric that forms the outer sheet of wrap 1.

Preferably, although each of the sheets 2 and 3 are air impermeable, they are each also formed of vapor permeable fabric. Their vapor-permeability serves to enable moisture from foot 100 to evaporate despite the foot wrap 1. This is especially preferable for sheet 3 so that perspiration adjacent bladder 9 can be evacuated from the site by the fluid that inflates and deflates bladder 9. The removal of surface moisture forming on the patient's skin beneath the foot wrap is beneficial since it helps promote the maintenance and healing of skin conditions, especially during protracted use.

Sheet 3 is preferably cut from the same or a similar pattern as sheet 2, so that it matches neatly with sheet 2. The manufacturing process may be simplified by first joining the sheets 2 and 3 together (as described elsewhere herein) and then cutting the border of each sheet. The cutting process may also be simplified by welding the two sheets together while simultaneously heat-cutting the border of the fabric with the same die (as is common in the art), although this process is not always successful due to the compositions of the sheets. Sheet 3 is preferably also a semi-elastic fabric, so that it expands more than outer sheet 2 when bladder 9 is inflated (as shown in Figure 6). The inner surface of sheet 3 (i.e., the surface facing toward sheet 2) is heat-weldable to enable bonding with the inner surface of sheet 2. It is important that the outer surface of sheet 3 (i.e., the surface facing away from sheet 2) is soft and comfortable against the skin, as that surface is likely to be in contact with the patient's skin during use. In the preferred embodiment, sheet 3 is a laminated trademark "LYCRA" material that meets the foregoing characteristics. As will be evident from this description to those of the ordinary skill in the art, other fabrics such as less costly nylon fabrics may be substituted with related sacrifices of various aspects of this invention.

Bladder 9 is formed between sheet 2 and sheet 3 by weld line 10. Weld line 10 is a closed line so that it completely surrounds and thereby defines a closed area on each of sheets 2 and 3. Thus, bladder 9 is a sealed bladder, the only inlet or outlet of which is provided by a

tubular connector fitting 11 (described below). Bladder 9 is provided in foot wrap 1 to apply pressure on the foot 100 when the wrap 1 is secured on the foot 100 and the bladder is inflated. Bladder 9 is of minimum size and volume consistent with its object of exerting pumping pressure on the foot and therefore requires a minimum volume of pressurized air per pulse. It is seen that although the bladder 9 occupies only the sole area of the foot 100, pressure and bladder expansion there causes the fabric enclosure around the foot to tighten and exert a compression force all around the arch region 101 of the foot 100. Bladder 1 is primarily intended for pneumatic inflation, although other fluids could be substituted by those of ordinary skill in the art.

In the first embodiment, bladder 1 is circular, roughly 3 to 5 inches in diameter. However, other shapes of bladders may be substituted while still employing many of the basic aspects of the invention. For instance, referring to a second embodiment as shown in Figures 7-10, an elongate bladder can be provided in an orientation that encircles the arch region 101 of the foot 100 when it is properly applied. The elongate bladder 9' of the second embodiment is slightly tapered (or may be pointed) near its opposite ends. The length of bladder 9' is sufficient such that its opposite ends will overlap each other when the wrap 1' is applied to a foot 100 of ordinary adult size. Other features of the second embodiment are substantially identical to like-numbered features of the first embodiment, and the corresponding descriptions of the first embodiment should be equally applicable to the second embodiment.

Referring again to the first embodiment, especially as shown in Figures 5 and 6, fitting 11 is a tubular fluid connector having an elbow form to reduce its height profile. Its elbow shape also enables connection of a fluid hose (not shown) to the fitting 11 and helps minimize the possibility of kinking such a hose during use. Conventional hose connectors may be incorporated in the outermost end of fitting 11 to enable connection of such a hose, although a properly sized hose can also be connected merely by a friction fit with fitting 11. Fitting 11 is formed of a

compatible heat-weldable material and has a base flange 12. This fitting is inserted through a hole punched in fabric sheet 2 so that flange 12 contacts the heat-weldable inner surface of fabric sheet 2 and is then welded fluid-tight to complete the bladder.

As mentioned, bladder 9 is formed in a main portion of foot wrap 1, and tabs (or “extensions”) 4, 5 and 7 extend generally away from the bladder 9. Tab 5 and a larger and longer extension 4 lie on opposite sides of the main portion that includes bladder 9, extending along the line “A–A.” Extension or tab 7 lies substantially perpendicular to line “A–A” and is considerably longer and narrower than tab 5. In other preferred embodiments (not shown), the tab 7 is more perpendicular than pictured in any of Figures 1-10. Edge 16 of tab 7 as shown in Figure 1 is aligned approximately tangent to the right hand (right in Figure 1) extremity of bladder 9. Hook patch 6 is sewn or welded at or near the distal end of tab 5 and is located, as shown in Figure 2, on the outer surface of inner sheet 3. The distal end of tab 7 is covered by a trademark “VELCRO” patch 8 in the same manner as tab 5 is covered with patch 6.

The outer perimeter 14 of the entire foot wrap 1 is RF-welded to form a single composite sheet with the single tubular fitting 11 mounted therein. This preferred embodiment weighs less than 6 ounces and is approximately 38 centimeters in the direction of line “A–A” of Figure 1 by 39½ centimeters in the perpendicular direction, which is in striking contrast to the large and complex foot wraps heretofore employed for this service. Other forms of connecting the sheets may be used, such as by stitching, although commensurate sacrifices of inventive aspects will be associated with such a change.

Foot wrap 1 also stands out for its ease and simplicity of use. Place the foot wrap in the flat position shown in figure 2, inner sheet 3 in contact with the foot, heel parallel to tab 7 and extending in the same direction as tab 7, wrap tab 4 around the arch of the foot and then wrap tab 5 over tab 4 where they overlap above the arch. Adjust the tightness of the fit to the degree desired and press the tip of tab 5 onto the outer surface of tab 4. This will enclose the foot in a

closed hoop of fabric. The relative length of tabs 4 and 5 are not fixed but must meet the requirement of overlapping sufficiently to form a secure fastening when wrapped around a foot. Thus, tab 4 may be shorter than tab 5, although the general proportion illustrated in Figures 1 and 2 are preferred. To maintain the positioning of the bladder just established, draw tab 7 around the back of the foot (or heel) and pull it snug. Hooked tip 8 is then pressed onto the outer surface of foot wrap 1 where it overlaps on the side of the foot. The foot wrap is now locked in position until the fastenings are peeled open for removal of the foot wrap. This procedure can be accomplished in a few seconds, and removal requires only pulling of the two tabs 5 and 7.

Position of the bladder 9 relative to the sole of the foot is easily seen and minor adjustments, if required, consist of loosening and repositioning one or both tabs 5 and 7 as necessary.

The foot wrap 1 will fit a wide range of foot sizes without change in the application technique. Feet of very small persons may be fitted through the use of firm padding above the instep and behind the heel to simulate a larger foot while allowing the bladder to act directly against the sole of the foot, as desired.

The foot wrap may be manufactured in both right and left handed form, if desired, although it is also envisioned within the scope of this invention that a single foot wrap can be interchangeable for both left and right feet.

An additional feature of the small, light foot wrap is that air can enter between the foot and the foot wrap from both the front and rear areas where the foot wrap wraps onto the foot. During the deflated phase of pumping, the fit is quite loose and air can easily diffuse the approximately 3 inch distance required to completely cover the area of skin beneath said foot wrap.

The soft inner surface of foot wrap 1, which is also the outer surface of sheet 3, may be covered with a springy, open pile or other lining which promotes the entrance of air into the area

between said foot wrap and the foot during the decompression phase. An alternative embodiment of the invention may use a non-vapor permeable sheet 3 having an outer surface with such air movement promoting characteristics.

This small, lightweight, inexpensive foot wrap fills an important need in modern medicine and fulfills all the objects set forth for the invention.

The foregoing preferred embodiments are but examples of the present invention. It should be noted that many modifications, variations, substitutions, equivalents, and alterations will be possible while still falling within the scope of this invention, as defined by the appended claims and as will be evident from the foregoing and following to those of ordinary skill in the art.

CLAIMS:

What is claimed is:

1. A medical device adapted for use with cyclical application of fluid pressure to apply said  
5 pressure to a human foot, said medical device comprising:

an interior elastic fabric sheet for engaging a human foot; and

an exterior non-extensible fabric sheet joined with said interior sheet in a manner  
forming a foot wrap, wherein:

said foot wrap comprises an inflatable bladder at an interior side of said exterior  
10 sheet; and

said interior sheet is adapted to exert a lateral force on said inflatable bladder  
such that said inflatable bladder is maintained substantially wrinkle free when applied to  
a human foot.

2. The medical device as recited in claim 1, wherein said inflatable bladder comprises at  
15 least a portion of said interior sheet.

3. The medical device as recited in claim 1, wherein said inflatable bladder is formed  
between said interior sheet and said exterior sheet, said inflatable bladder consisting essentially  
20 of a portion of said interior sheet, a portion of said exterior sheet and an inlet for inflation  
thereof.

4. The medical device as recited in claim 3, wherein said inlet comprises a tubular fluid connector opening into said inflatable bladder and suitable for connecting said inflatable bladder in fluid communication with a source of pressurized fluid for cyclical application of fluid pressure to a human foot.

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5. The medical device as recited in claim 3, wherein said portion of said interior sheet and said portion of said exterior sheet are perimetrically sealed to form said inflatable bladder.

6. The medical device as recited in claim 5, wherein said inflatable bladder is formed by heat-welding said interior sheet to said exterior sheet.

10

7. The medical device as recited in claim 3, wherein said interior sheet comprises a vapor permeable construction.

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8. A medical device adapted for use with cyclical application of fluid pressure to apply said pressure to a human foot, said medical device comprising:

an interior elastic fabric sheet for engaging a human foot;

an exterior non-extensible fabric sheet joined with said interior sheet in a manner forming an foot wrap having an integral bladder formed between said interior sheet and said exterior sheet;

20

a first tab for releasably securing said foot wrap to a human foot by wrapping around the arch; and

an elongate second tab for releasably securing said foot wrap to a human foot by wrapping around the heel.



9. The medical device as recited in claim 8, wherein said second tab is generally perpendicular to said first tab when said foot wrap is laid flat.

10. The medical device as recited in claim 9, said medical device further comprising a third  
5 tab, said third tab being generally opposed to said first tab.

11. The medical device as recited in claim 10, wherein:

said exterior sheet consists essentially of a hook-type connector compatible base material;

10 said first tab comprises a first releasable hook-type connector permanently attached to an inner surface of a distal end thereof, said first and third tabs having dimensions sufficient for said foot wrap to wrap completely around the arch of a human foot with the distal end of said first tab overlapping a distal end of said third tab; and

15 said second tab comprises a second releasable hook-type connector permanently attached to an inner surface of a distal end thereof, said second tab having a length dimension sufficient for said foot wrap to wrap completely around the heel of a human foot with the distal end of said second tab overlapping said first tab when said first and third tabs are wrapped about the arch of a human foot.

12. The medical device as recited in claim 10, wherein:

said exterior sheet consists essentially of a hook-type connector compatible base material;

said third tab comprises a first releasable hook-type connector permanently attached to an inner surface of a distal end thereof, said first and third tabs having dimensions sufficient for said foot wrap to wrap completely around the arch of a human foot with the distal end of said third tab overlapping a distal end of said first tab; and

said second tab comprises a second releasable hook-type connector permanently attached to an inner surface of a distal end thereof, said second tab having a length dimension sufficient for said foot wrap to wrap completely around the heel of a human foot with the distal end of said second tab overlapping said first tab when said first and third tabs are wrapped about the arch of a human foot.

13. A medical device adapted for use with cyclical application of fluid pressure to apply said pressure to a human foot, said medical device comprising:

a foot wrap for engaging a human foot, said foot wrap having an integral inflatable bladder and an outer surface consisting essentially of a hook-type compatible base material;

a first tab appended to said foot wrap for releasably securing said foot wrap to a human foot by wrapping around the arch; and

an elongate second tab appended to said foot wrap for releasably securing said foot wrap to a human foot by wrapping around the heel.

14. The medical device as recited in claim 13, wherein said second tab is generally perpendicular to said first tab when said foot wrap is laid flat.

15. The medical device as recited in claim 14, said medical device further comprising a third tab appended to said foot wrap, said third tab being generally opposed to said first tab.

16. The medical device as recited in claim 15, wherein:

5 said first tab comprises a first releasable hook-type connector permanently attached to an inner surface of a distal end thereof, said first and third tabs having dimensions sufficient for said foot wrap to wrap completely around the arch of a human foot with the distal end of said first tab overlapping a distal end of said third tab; and

10 said second tab comprises a second releasable hook-type connector permanently attached to an inner surface of a distal end thereof, said second tab having a length dimension sufficient for said foot wrap to wrap completely around the heel of a human foot with the distal end of said second tab overlapping said first tab when said first and third tabs are wrapped about the arch of a human foot.

17. A medical device adapted for use with cyclical application of fluid pressure to apply said pressure to a human foot, said medical device comprising:

an interior elastic fabric sheet for engaging a human foot;

an exterior non-extensible fabric sheet consisting essentially of a hook-type connector compatible base material, said exterior sheet being joined with said interior sheet in a manner forming a one-piece foot wrap having:

an integral inflatable bladder formed between the inner surfaces of said interior and exterior sheets;

a first tab for releasably securing said foot wrap to a human foot by wrapping around the arch;

an elongate second tab for releasably securing said foot wrap to a human foot by wrapping around the heel, said second tab being generally perpendicular to said first tab when said foot wrap is laid flat;

a third tab generally opposed to said first tab; and

a main portion positioned generally between said first, second and third tabs;

a first releasable hook-type connector permanently attached to an inner surface of a distal end of said first tab, said first and third tabs having dimensions sufficient for said foot wrap to wrap completely around the arch of a human foot with the distal end of said first tab overlapping a distal end of said third tab;

a second releasable hook-type connector permanently attached to an inner surface of a distal end of said second tab, said second tab having a length dimension sufficient for said foot wrap to wrap completely around the heel of a human foot with the distal end of said second tab overlapping said main portion.

18. The medical device as recited in claim 17, wherein the inner surface of said exterior sheet comprises a heat-weldable laminate and the inner surface of said interior sheet comprises a heat-weldable laminate, said exterior sheet being heat-welded to said interior sheet to form said one-piece foot wrap.

5

19. The medical device as recited in claim 18, said medical device further comprising a tubular fluid connector opening into said integral inflatable bladder and suitable for connecting said integral inflatable bladder in fluid communication with a source of pressurized fluid for inflating said integral inflatable bladder.

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ABSTRACT OF THE DISCLOSURE:

A medical device having an expandable fluid-tight bladder formed integral within a wrap (or sheath) that can be securely fastened onto a human foot. The foot wrap positions and holds the bladder under the arch of the foot so as to compress the sole area when the bladder is inflated.

- 5 The foot wrap is soft, lightweight, flexible and suitable for extended wear with minimum discomfort. It can be readily used with a pneumatic or hydraulic pressure applicator or cyclic pump to promote blood circulation in the legs of bedridden patients.

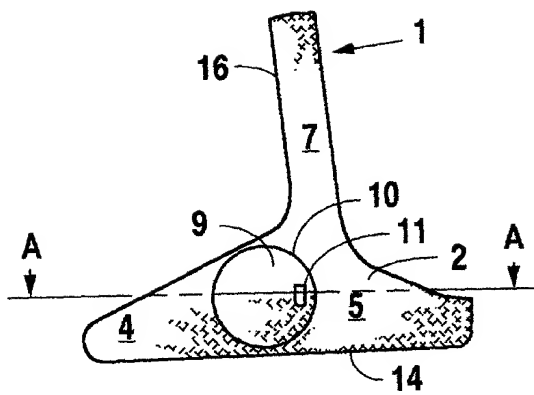


Fig. 1

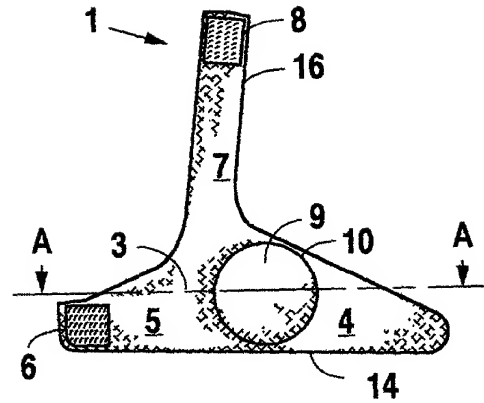


Fig. 2

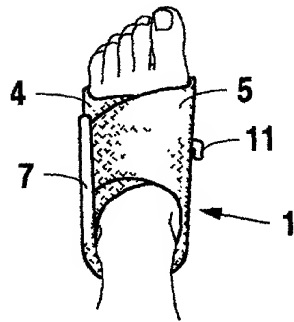


Fig. 3

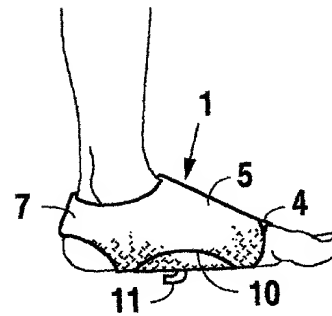


Fig. 4

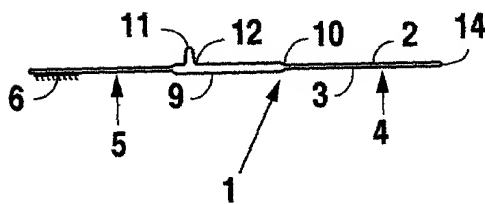


Fig. 5

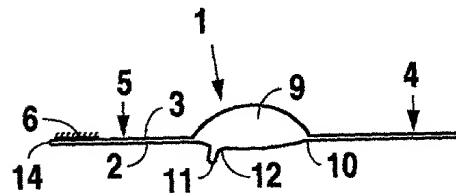


Fig. 6

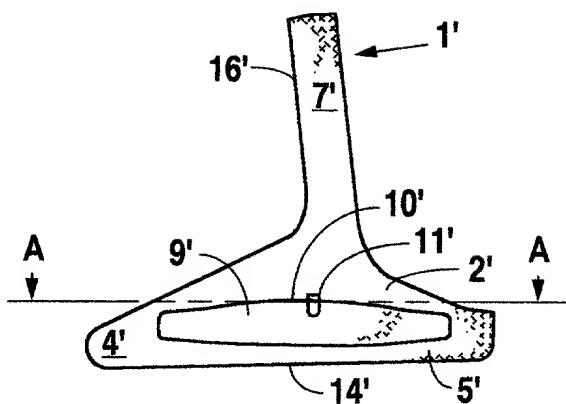


Fig. 7

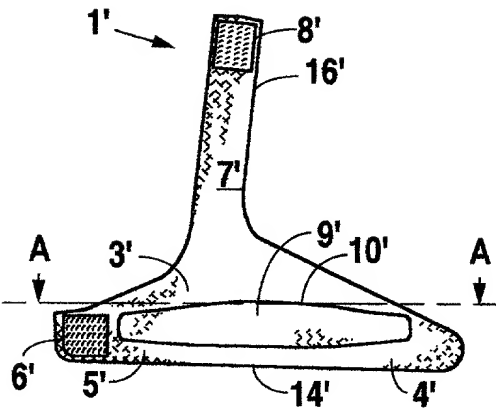


Fig. 8

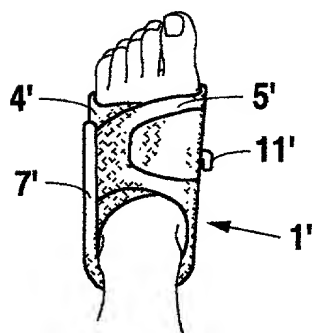


Fig. 9

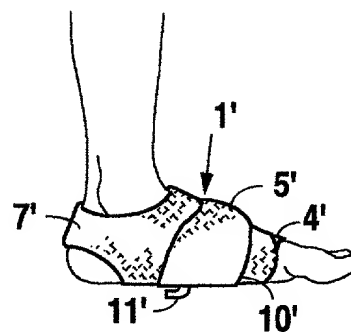


Fig. 10



**DECLARATION, POWER OF AGENT AND CORRESPONDENCE ADDRESS**

As a below named inventor, I hereby declare that:

This declaration is of the following type:

- ☒ original
- ☐ design
- ☐ supplemental
- ☐ national stage of PCT

My residence address, post office address, and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

“FOOT MOUNTED VENOUS COMPRESSION DEVICE”

the specification of which:

- ☒ is attached hereto.
- ☐ was filed on \*\*\* as Application Serial No. \*\*\* and was amended on \*\*\* (if applicable).
- ☐ was described and claimed in PCT International Application No. \*\*\* filed on \*\*\* and as amended under PCT Article 19 on \*\*\* (if any).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information known to be material to the patentability of any claim in accordance with 37 CFR §1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.

**CERTIFICATE OF MAILING BY “EXPRESS MAIL” (37 CFR §1.10)**

“Express Mail” Mailing Label No: EL331367359US

Date of Deposit: November 2, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service “Express Mail Post Office to Addressee” service, under 37 CFR §1.10, on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

11/2/99  
Date:

  
Signature of Person Mailing

Brian Goode  
Printed Name of Person Mailing

### FOREIGN PRIORITY

I hereby claim foreign priority benefits, under 35 USC §§119(a)-(d) or §365(b), of any foreign application for patent or inventor's certificate or, under §365(a), of any PCT international application designating at least one country other than the United States of America listed below. I have also identified below any related foreign application for patent or inventor's certificate or PCT international application having a filing date before that of the application(s) to which priority is claimed.

*Prior Foreign Applications(s):*

\*\*\*

### DOMESTIC PRIORITY

This application is of the following type:

- ( ) original
- ( ) divisional
- (X) continuation
- ( ) continuation-in-part (CIP)

I hereby claim domestic priority benefits, under 35 USC §§119(e) and/or 120, of any United States application or, under §365(c), of any PCT international application designating the United States of America listed below. To the extent that the subject matter of any claim of this application is not disclosed in the below listed prior United States or PCT international application(s) in the manner required under the first paragraph of 35 USC §112, I acknowledge the duty to disclose material information, as defined in 37 CFR §1.56, which occurred between the filing date(s) of the prior application(s) and the national or PCT international filing date of this application.

*Prior Domestic Application(s):*

U.S. patent application Serial No. 08/816,807 filed March 19, 1997  
U.S. patent application Serial No. 08/428,268 filed April 25, 1995  
U.S. patent application Serial No. 08/275,920 filed July 14, 1994  
U.S. patent application Serial No. 08/000,545 filed January 4, 1993  
U.S. patent application Serial No. 07/766,576 filed September 27, 1991

### STATEMENT UNDER 18 USC §1001

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001 and that such willful false statements may jeopardize the validity of this application or any patent which may issue thereon.

### POWER OF AGENT

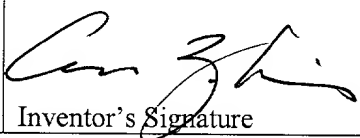
As a below named inventor, I hereby appoint Wayne J. Colton, Registration No. 40,962, as principal agent of record and William H. Quirk, IV, Registration No. 33,996 as principle attorney of record, jointly and severally, each with full power of substitution and revocation, to transact all business before the U.S. Patent and Trademark Office in connection with the above-identified patent application.

DESIGNATION OF CORRESPONDENCE ADDRESS

Please send all correspondence and direct all telephone calls to **CUSTOMER NO. 22775:**

Wayne J. Colton  
WAYNE J. COLTON, INC.  
The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205

Telephone: 210 222 8455  
Telecopier: 210 222 8445

1	Cesar Z. LINA		November 7, 1999
	Full Name	Inventor's Signature	Date
	Universal City, Texas USA	USA	
	Residence	Citizenship	
	8511 Aesop Lane Universal City, Texas 78148 USA		
	Post Office Address		

2			
	Full Name	Inventor's Signature	Date
	Residence	Citizenship	
	Post Office Address		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Cesar Z. LINA

Serial No.: \*\*\*

Filed: November 2, 1999

Title: FOOT MOUNTED VENOUS  
COMPRESSION DEVICE

§  
§ Group Art Unit: \*\*\*  
§  
§ Examiner: \*\*\*  
§  
§  
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POWER OF AGENT AND INTERVENTION OF ASSIGNEE

Box Patent Application  
Assistant Comm'r for Patents  
Washington, D.C. 20231

Sir:

The undersigned, being the Assignee of the entire right, title and interest in the above-captioned patent application, hereby elects, under 37 CFR §3.71, to prosecute this patent application to the exclusion of the inventors. In accordance with the provisions of 37 CFR §3.73(b), a certificate in evidence of the undersigned Assignee's title is submitted herewith. A power of agent and designation of correspondence address follows.

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR §1.10)

"Express Mail" Mailing Label No: EL331367359US

Date of Deposit: November 2, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, under 37 CFR §1.10, on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date:

11/2/99

Signature of Person Mailing

Brian Goode

Printed Name of Person Mailing

**POWER OF AGENT**

The Assignee hereby revokes any previous power of attorney or agent and hereby appoints Wayne J. Colton, Registration No. 40,962 as principle agent of record and William H. Quirk, IV, Registration No. 33,996 as principle attorney of record, jointly and severally, each with full power of substitution and revocation, to prosecute this application, to make alterations and amendments thereto, and to transact all business in the Patent and Trademark Office.

**DOCKET NUMBER AND ADDRESS FOR CORRESPONDENCE**

Please update the docket number for the above-captioned application to 1001.1096 and direct all future correspondence and communications relevant the same to **CUSTOMER NO. 22775:**

Wayne J. Colton  
WAYNE J. COLTON, INC.  
The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205  
Telephone: 210 222 8455  
Telecopier: 210 222 8445

Respectfully submitted,

KINETIC CONCEPTS, INC.

Name: John H. Vrzalik

Title: Vice President

John H. Vrzalik  
Signature

11-2-99  
Date

**CERTIFICATE UNDER 37 CFR §3.73(b)**

Assignee(s): KINETIC CONCEPTS, INC. (A Texas corporation with principle place of business in San Antonio, Texas.)

The above-identified individual(s), or other legal entity or entities, hereby certifies that, to the best of his, her or its knowledge and belief, he, she or it is the Assignee of the entire right, title and interest in the following identified patent or patent application:

- ( ) U.S. patent No.: \*\*\*  
(X) U.S. patent application:  
( ) Serial No.: \*\*\*  
(X) Title: FOOT MOUNTED VENOUS COMPRESSION DEVICE; Filing Date: November 2, 1999; Inventor(s): Cesar Z. LINA

by virtue of:

- ( ) an assignment from the inventor(s), or previous assignee(s) in full, of the above-identified patent or patent application,  
( ) recorded in the U.S. Patent and Trademark Office at Reel \*\*\*, Frame(s) \*\*\*.  
( ) a copy of which is attached.  
(X) an assignment from the inventor(s), or previous assignee(s) in full, of the following identified patent or patent application, of which the above-identified patent or patent application is a divisional, continuation or continuation-in-part:  
( ) U.S. patent No.: \*\*\*,  
(X) U.S. patent application:  
(X) Serial No.: 07/766,576,  
( ) Title: \*\*\*; Filing Date: \*\*\*; Inventor(s): \*\*\*,  
(X) recorded in the U.S. Patent and Trademark Office at Reel 5978, Frame(s) 0487-89.  
( ) a copy of which is attached.

**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR §1.10)**

"Express Mail" Mailing Label No: EL331367359US

Date of Deposit: November 2, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, under 37 CFR §1.10, on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

11/2/99  
Date:

  
Signature of Person Mailing

Brian Goode  
Printed Name of Person Mailing

( ) a chain of title from the inventor(s), or previous assignee(s) in full, of the above-identified patent or patent application to the current assignee as shown below:

(1) From: \*\*\*  
To: \*\*\*

- ( ) Document recorded in the U.S. Patent and Trademark Office at Reel \*\*\*,  
Frame(s) \*\*\*.  
( ) Document attached hereto.

(2) From: \*\*\*  
To: \*\*\*

- ( ) Document recorded in the U.S. Patent and Trademark Office at Reel \*\*\*,  
Frame(s) \*\*\*.  
( ) Document attached hereto.

(3) From: \*\*\*  
To: \*\*\*

- ( ) Document recorded in the U.S. Patent and Trademark Office at Reel \*\*\*,  
Frame(s) \*\*\*.  
( ) Document attached hereto.

- ( ) Additional document(s) in the chain of title are listed on a supplemental sheet.  
( ) Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all of the documents in the above-recited chain of title for the above-identified patent or patent application and, to the best of the undersigned's knowledge, title rests in the above-identified Assignee.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the Assignee.

I hereby declare that all statements herein made of my own knowledge are true and that all statements made on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001; and that any such willful false statement so made may jeopardize the validity of the above-identified patent or patent application or any patent issued thereon.

Name: John H. Vrzalik

Title: Vice President

John H. Vrzalik  
Signature

11-2-99  
Date